UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE GENERAL MILLS
INC. KIX CEREAL
LITIGATION

Case No. 12-249 (KM) (JBC)

EXPERT DECLARATION OF CHARLES M. BENBROOK, PH.D. IN SUPPORT OF PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT

Dated: June 19, 2015

I. <u>INTRODUCTION</u>

- 1. Plaintiffs allege in this litigation that the "Made with All-Natural Corn" claim made by General Mills on packages of Kix cereals between 2009 and 2013 was false.
- 2. I have been asked by Plaintiffs' counsel to provide this Declaration to assist the Court in determining whether a genuine dispute of material fact exists concerning the alleged falsity of the "Made with All-Natural Corn" claim on Kix cereals.
- 3. The statements of fact and conclusions presented in this Declaration are based primarily on:
 - a. scientific, technical, and other specialized knowledge I have acquired during more than a 30 year career in the field of agricultural science, technology, risk assessment, and regulation (detailed in Section III, below);
 - b. my scientific and technical knowledge of the impacts of the genetic engineering process on the composition of the corn, and corn-based ingredients, from which Kix cereals have been, and still are manufactured;
 - c. documents produced by General Mills to Plaintiffs describing the corn and corn-derived ingredients purchased by General

Mills for use in Kix cereals (cited in Appendix C; Declaration of Meagan Keenan, dated June 19, 2015 ("Keenan Decl."), Ex. 25);

- d. the deposition testimony of General Mills employee Sarah

 Geisert (cited in Appendix C; Keenan Decl., Ex. 8); and
- e. the patents covering the major genetically engineered corn varieties used in the manufacture of Kix cereal, and the processes used to create those corn varieties (provided in Appendix C).
- 4. Appendix A to this Report contains my resume outlining my professional experience, qualifications, and publications I have written, or helped write in the previous ten years.
- 5. Appendix B to this Report lists cases in which I have prepared an expert report, or testified as an expert at trial or by deposition.
- 6. Appendix C to this Report lists additional documents that I have referenced and/or considered in reaching my factual findings and opinions in this Report.
- 7. This declaration is based upon the information and data presently available to me. I reserve the right to update or supplement this Declaration as new information becomes available.

8. I am being compensated at the rate of \$300 per hour for my work on this case.

II. SUMMARY OF CONCLUSIONS

- 9. Based on my knowledge of genetic engineering, the U.S. corn market and supply chains for corn-derived ingredients between 2009-2013, and information provided to Plaintiffs by General Mills concerning the company's purchases of corn ingredients, I conclude that:
 - a. The majority of the corn used to make Kix was genetically engineered (GE) corn.¹
 - b. The majority of the corn used to make Kix was "Roundup Ready corn" (corn genetically engineered to withstand application of the widely used herbicide glyphosate, sold by Monsanto under the name "Roundup," which would otherwise kill the corn plants).
 - c. The majority of corn used to make Kix was also "Bt corn" (corn genetically modified to produce Bacillus thuringiensis ("Bt") pesticidal proteins inside the plants, making the corn plants

¹ Unless otherwise specified, the statements and descriptions in this Declaration regarding the corn used to make Kix cereals, and the genetic modifications used to create that corn, cover at least the period 2009-2013.

- toxic to certain insects that would otherwise feed on, and damage the plants).
- d. Roundup Ready corn and *Bt* corn (as well as other GE corn varieties) are created through a complex, multi-step process, conducted by humans, in which DNA extracted from organisms of different species is spliced together into a synthetic DNA unit (called a "transgene"), which is then inserted into the corn plant's existing DNA, causing the plant to exhibit a trait (or traits) that never before existed in the target plant.
- e. Several of the individual steps in the genetic engineering process, and especially the sequence of steps, are inherently unnatural, by which I mean that they have no counterpart in nature and will never be replicated in the natural world without direct human intervention.
- f. The synthetic transgenes inserted into corn DNA to create Roundup Ready and *Bt* corn are inherently unnatural as well, as the chance they will be replicated in the natural world without direct human intervention is virtually zero.
- 10. Patents held by Monsanto covering DNA sequences and processes used to create Roundup Ready and *Bt* corn explicitly describe certain DNA

sequences and parts of the genetic engineering process as "non-natural," "artificial," and "synthetic."

III. SUMMARY OF QUALIFICATIONS

- 11. I received my M.A. and Ph.D. degrees in agricultural economics from the University of Wisconsin-Madison in 1979/1980. I received a B.A. degree in economics from Harvard University in 1971.
- 12. I have worked in the field of agricultural systems, technology, risk assessment and regulation for more than 30 years, specifically regarding the impact of agricultural technology on pesticide use, pesticide efficacy, risks, and costs, as well as on the impacts of regulatory policies, requirements, actions, and laws on pest management systems, pesticide use and risks, and food quality and safety.
- 13. I was the Staff Director for the House subcommittee with jurisdiction over the "Federal Insecticide, Fungicide, and Rodenticide Act" (FIFRA) from 1981-1983. During this period, hearings were held on the "Organic Food Production Act" legislation that became part of the 1990 farm bill. A critical issue at that time was the difference between "organic" and "natural" foods. Indeed, this foundational question has remained a focus of research on food production systems, and food manufacturing and labeling policy over the last 25 years.
- 14. In 2007, I published a peer-reviewed paper in a book entitled Biodiversity & the Law: Intellectual Property, Biotechnology & Traditional

Knowledge (McManis ed., 2007, Earthscan). My chapter was entitled "Principles Governing the Long-Run Risks, Benefits and Costs of Agricultural Biotechnology" (pp. 149-167, see Appendix B). I discuss principles that should be applied to any technology in evaluating its possible or actual impacts. The characteristics of today's GE crops were appraised relative to a set of "first principles" for safe and sustainable agriculture, both in the U.S. and in developing countries.

- 15. As the Chief Scientist of The Organic Center (2006-2012), I was responsible for tracking developments in the scientific literature, government agencies, the food industry, and non-profit organizations that were likely to impact consumer understanding of, and confidence in, the USDA "certified organic" seal that appears on the labels of certified organic food products.
- 16. I have actively participated in public and private sector efforts to develop and implement policies and procedures sufficient to prevent the contamination of organic crops and food with genetically altered DNA from commercial or experimental GE crops.
- 17. I serve on the USDA's AC-21 Agricultural Biotechnology Advisory Committee. That committee issued a report in 2013 on "coexistence" between farmers planting fields to organic, conventional non-GE, and GE crops. I also served in 2010-2011 on a USDA working group assessing coexistence issues specific to a type of genetically altered alfalfa under review by the USDA.

- 18. I have served for six years on the technical standards committee of the Non-GMO Project. The Non-GMO Project is a non-profit 501(c)3 organization that manages a labeling program verifying the absence of GE content in food products, based on specific technical parameters and testing requirements set forth by the organization. Food products that meet the Non-GMO Project's technical parameters are authorized by the organization to bear the "Non-GMO Verified" label.
- 19. I have studied the content and impacts of Food and Drug Administration (FDA) assessments of the safety of GE crops, and Environmental Protection Agency (EPA) pesticide program decisions and policies relevant to insect-protected, *Bt* GE crops and herbicide-tolerant GE crops. I have reviewed and developed detailed comments on a significant share of the health, safety, and environmental impact data submitted by GE technology developers to U.S. government agencies.
- 20. I worked as a consultant for the California State Department of Pesticide Regulation and carried out a comprehensive pesticide regulatory program evaluation between 1991-1993.
- 21. I have studied for many years the impacts of the commercialization of GE crops on pest management systems and pesticide use (encompassing both the

use of insecticides and herbicides, and the volume of *Bt* proteins produced by GE, insect-protected corn and cotton).

- 22. I have completed several reports on the impact of GE crops on pesticide use in the U.S., and published a peer-reviewed paper on this topic in 2012 (*see* Appendix B: Benbrook, 2012, "Impact of genetically engineered crops on pesticide use in the U.S. the first sixteen years").
- 23. Since 1990, I have been President of Benbrook Consulting Services, a small consulting firm conducting projects on agricultural technology, food safety and quality, and pesticide use and regulation.
- 24. For a variety of Benbrook Consulting Services clients since the mid-1990s, I have reviewed many petitions and other documents submitted by biotechnology companies seeking government approval (often referred to as "deregulation") for new GE crops.
- 25. I have also followed the scientific literature on the genetic characterization of GE crops and food, GE crop/food risk assessment, GE crop/food testing methods, and GE crop efficacy, costs, safety, environmental impacts, nutritional equivalence, and socio-economic impacts.

IV. KIX CEREALS WERE, AND ARE, MADE FROM GENETICALLY ENGINEERED CORN

A. The Vast Majority of Corn in the U.S. Food Supply Chain is Genetically Engineered

- 26. Genetic engineering ("GE", or "bioengineering") is a complex, multistep process, conducted by humans, in which DNA extracted from organisms of several species is spliced together, moved into, and combined with a plant's existing DNA, causing the recipient plant to exhibit traits that it never has been able to obtain, or express.
- 27. The U.S. Department of Agriculture (USDA) publishes reliable data, updated annually, on the percent of acreage planted to GE corn varieties that are insect-resistant (*Bt*) only, herbicide-tolerant (such as Roundup Ready) only, and so-called "stacked gene varieties," which contain GE traits for both herbicide tolerance and insect resistance.²
- 28. The percentage of national corn acres planted to GE varieties ranged from 25% to 34% in the 1999-2002 period, and then began increasingly rapidly,

² Many stacked gene varieties of corn contain more than two GE traits. Monsanto, for example, sells corn containing two herbicide tolerance traits plus as many as six different *Bt* traits (that is, containing six different DNA segments from *Bacillus thuringiensis*, each allowing the plant to produce a different insecticidal endotoxin) targeting different insects. By 2010, the average GE corn seed planted in the U.S. expressed about four traits, and in 2014, the average likely exceeded five traits.

reaching 52% in 2005, 80% in 2008, and 93% in 2014 (see Appendix C; Keenan Decl., Ex. 26).

- 29. The percent of national corn acres planted to stacked trait varieties (*i.e.*, those containing at least one insect-tolerance trait and at least one herbicide resistance trait), increased from 6% in 2004 to 28% in 2007, 46% in 2009, and 76% in 2014. Most GE corn planted in the U.S. between 2009 and 2013 was genetically engineered to produce one or more *Bt* endotoxins, and to resist Roundup herbicide application.
- 30. In the industrial food supply chain, non-GE corn and products derived from non-GE corn are typically segregated from GE corn products, and designated either as "identity preserved" or "certified organic." "Identity-preserved" corn is non-GE corn that does not meet the more stringent requirements to qualify as "certified organic."
- 31. Identity-preserved and organic corn (and corn products) cost significantly more than open-market (GE) corn and corn products (generally at least 20% more for non-GE corn/products, and 100% to 200% more for certified organic corn/products).
- 32. The vast majority of GE corn and corn products are sold as undifferentiated commodities in "open source" markets, which are not designated as "identity preserved" or "certified organic."

- 33. While relatively small amounts of non-GE corn may be commingled with the GE corn in the open source corn supply, it is universally understood in the industry that open source corn is primarily GE corn, especially since 2009.
- 34. Corn from many different sources is commingled at various points in the open source supply chain. For example, each shipment of corn by rail or barge into plants milling corn grain for eventual sale of corn meal to General Mills typically includes corn from several dozen fields. Multiple corn shipments are often then commingled in large storage bins at milling facilities. After the grain is milled, the flour or meal may be commingled again with other milled grain that initially came from other storage bins.
- 35. Due to the high proportion of GE corn in the open-source corn supply chain, and the extensive commingling of the corn entering and moving along open-source supply chains, it is extremely unlikely that any shipment of corn, corn meal, or other corn-derived ingredient purchased by General Mills was free of the genetically engineered proteins in GE corn.

B. General Mills Did Not Purchase Non-GE Corn for Use in Kix Cereals.

36. The primary ingredients in Kix cereals between 2009-2013 were, and

still are, "Whole Grain corn" and "corn meal."³

- 37. General Mills did not seek to purchase non-GE corn or corn ingredients for the manufacture of Kix, according to the deposition testimony of General Mills given by Sarah Geisert. (*See* Appendix C; Keenan Decl., Ex. 8).
- 38. Documents produced to Plaintiffs by General Mills (*see* Appendix C; Keenan Decl., Ex. 25) indicate that the corn, corn meal and other corn-based ingredients purchased by General Mills for use in Kix cereals were from "open sources" and were not "identity preserved" or "certified organic."
- 39. The proportion of GE corn in "open source" corn ingredients that General Mills purchased for use in Kix cereals can be approximated by reference to the percentages of total corn acres planted each year to GE corn varieties as reported by the USDA-ERS. (*See* Appendix C; Keenan Decl., Ex. 26)
- 40. Since 2009, a majority of the corn moving through corn-derived ingredient supply chains, and ultimately purchased by General Mills for use in Kix cereals, was genetically engineered.
- 41. In addition, I am informed by Plaintiffs' counsel that General Mills has admitted that (i) it does not specifically source non-GE corn for use in Kix

³ See Appendix C; Keenan Decl., Ex. 7 (GMI_KIX00000150; GMI_KIX00000186; GMI_KIX00000191).

cereal, and (ii) some of the corn used in Kix cereal was grown from seed produced through bioengineering.

- 42. Based on the above information, my knowledge of the U.S. corn market and supply chains for corn-derived ingredients, and the case materials reviewed to date reflecting General Mills' purchases of corn ingredients in conventional, open-sourced markets, it is highly likely that:
 - a. the proportion of GE corn in the whole corn and corn-derived ingredients purchased by General Mills for use in Kix cereals during the period 2009-2014 exceeded 80%; and
 - b. the proportion of GE corn in those products that included "stacked" trait genetic modifications for both insect pest-resistance and herbicide-tolerance likely averaged well over 50% from 2009-2014.
- 43. Given the high proportion of GE corn in the corn-derived ingredients used in Kix cereals, and the extensive commingling of corn from various sources in the open source supply chain, it is virtually certain that all boxes of Kix cereal sold between 2009-2013 were manufactured at least in part from GE corn.

V. THE GENETIC ENGINEERING PROCESS

A. Background

- 44. The common feature of today's commercial, GE corn varieties relevant to this case is that they have all been genetically engineered to express traits reliant upon genes from outside the corn genome (*i.e.*, genetic code). By "outside" the plant's genome, I mean a gene, or genetic trait, that has never been known to enter a corn plant's heritable genome via normal reproductive and/or plant breeding processes. Each GE trait added to corn is ostensibly intended to confer some crop management advantage for farmers who plant the GE seeds, or provide some other benefit for the food companies that utilize the harvested crops in various manufacturing processes (*e.g.*, altered fatty acid profiles, or longer stability when refined oils are used to fry foods).
- 45. The widespread planting of GE crops is also a matter of controversy, with experts expressing concerns including: risk of unforeseen effects on ecosystems and the environment, increased reliance on and use of herbicides (particularly glyphosate), and possible, though still unproven, long-term health effects.⁴

⁴ Due to the prevalence of Roundup Ready crops, the agricultural use of the herbicide glyphosate has increased significantly from 27.5 million pounds in 1995 (the year before GE crops were introduced) to 250 million pounds in 2014—a 9.1-fold increase. Concerns about the effects of glyphosate have likewise been increasing. The World Health Organization's cancer research arm recently

B. Genetic Engineering Terminology

- 46. The following definitions and explanations are intended to assist non-scientists in gaining a basic understanding of the GE process:
 - a. **Genome:** Every individual of a plant species a rose, carrot, corn, or apple tree has a unique genetic makeup, often referred to as the plant's *genome*, which is encoded in the plant's DNA. "*Genome*" refers to the full genetic code that controls for all the characteristics, traits, and biochemical pathways that exist within a species of plant. Closely related plant species a Fuji apple compared to a McIntosh have highly similar genomes, but differences in a handful of genes can result in one apple being red and sweet, the other green and tart, and so on across other differences.
 - b. **DNA Sequence**: A *DNA sequence* is a piece of DNA made up of a number of constituent "building block" molecules (called

declared glyphosate to be a probable human carcinogen. Kathryn Guyton, et al, Int'l Agency for Research on Cancer Monograph Working Group, *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon, and Glyphosate*, 16 The Lancet Oncology 490 (2015), *available at*: http://dx.doi.org/10.1016/S1470-2045(15)70134-8; *see also* Daniel Cressey, *Widely Used Herbicide Linked to Cancer*, Scientific American (March 25, 2015), available at: http://www.scientificamerican.com/article/widely-used-herbicide-linked-to-cancer/.

- nucleotides). *Some* DNA sequences are fully functional "genes" that code for particular traits or functions. There are other DNA sequences that are not fully functioning genes.
- c. **Donor Organism**: The *donor organism* is the organism from which the foreign DNA is extracted.
- d. **Event**: A GE *event* refers to a specific, genetically engineered strain of plants that is the result of the successful movement of a transgene into a plant's genome. For every GE technology on the market (*e.g.*, glyphosate-tolerant corn), there can be one or more *events* incorporated in the commercial, GE-corn varieties sold to farmers.
- e. **Foreign DNA:** In the context of the genetic engineering of plants, *foreign DNA* are genes and/or genetic elements that come from outside a plant's genome (*i.e.*, do not exist within the plant's genome).
- f. **Gene**: A *gene* is an intact DNA sequence containing the code for a particular trait or function.
- g. **Genetic Element**: A *genetic element* is a piece of DNA that is a fragment of a fully functional gene that serves a regulatory function, such as turning a specific gene on or off. **Introns** are

genetic elements used to, among other things, direct the expression of foreign DNA in a target plant to a particular part of the plant.

- h. **Herbicide-Tolerant**: An *herbicide-tolerant (HT)* crop variety has either been conventionally bred or genetically engineered to withstand applications of a specific herbicide, or family of herbicides, that would otherwise kill or severely damage the crop plant.
- i. **Insect-Protected**: An *insect-protected* crop variety has either been conventionally bred or genetically engineered to repel insects, kill them, or block their reproduction or morphological development, rendering them unable to cause economic damage to plants in farm fields. All of today's commercially significant, insect-protected GE corn crops are engineered to express *Bacillus thuringiensis* (*Bt*) endotoxins⁵ that cause breaks and abrasions in an insect's gastrointestinal tract, leading

⁵ The endotoxins produced in Bt corn cells are pore-forming, crystalline proteins that are toxic to certain insects. When a susceptible insect ingests these proteins, they are activated by proteolytic cleavage, and gradually create holes in the insect's stomach, leading to dehydration and death.

- to death. *Bt*-transgenic is another phrase commonly used to describe GE corn expressing *Bt* genes.
- j. **Promoters and Terminators**: *Promoters* are DNA sequences that control when a gene is turned on (expressed), and at what level. *Terminators* are DNA sequences that control when a gene is turned off. Both Promoters and Terminators are referred to as regulatory sequences (or regulatory genes).
- k. **Target Organism**: The *target organism* is the organism into which the foreign DNA is inserted.
- 1. **Transgene:** A *transgene* is a synthetic combination of genes, promoters, terminators, and other genetic elements that is created in the lab, and that contains the foreign DNA that the genetic engineer hopes to move into a plant, where it will hopefully be expressed, conferring a new trait. Transgenes are sometimes referred to as a "gene construct" or "gene cassette."
- m. **Transgenic:** A *transgenic* plant is one modified through insertion of foreign DNA. The foreign DNA become part of the plant's genome, and confers a heritable trait within the now-genetically-engineered plant genome.

C. The Process Of Modifying Agricultural Crops Through Genetic Engineering

- 47. The GE process consists of several steps including: (1) identifying genes of interest that are associated with, or express, a potentially useful trait; (2) acquiring a copy of the gene(s); (3) amplifying the expression of the genes (usually first in bacteria); (4) manipulating the gene to enhance functionality in the target crop into which the gene is being inserted; (5) moving the gene into the crop; (6) selecting cells or crop tissue that contain working copies of the gene (*i.e.*, tissues where the transgene is being expressed); (7) regenerating a full, mature plant that produces viable seed from the engineered tissue; and (8) assuring that the inserted gene is functioning properly and does not cause any unexpected problems.
- 48. All these steps are distinct from what happens in nature as plants reproduce, and/or as evolutionary forces trigger mutations and diversification in plant species over very long periods of time.
- 49. Steps (4) through (6) of the above-described GE process, individually and collectively, are inherently synthetic and unnatural, because each of these steps requires actions by people that alter foreign DNA in ways not possible in nature, combining foreign DNA from multiple, unrelated organisms into a transgene, and then incorporating that inter-linked foreign DNA into a target organism in a manner impossible to achieve through natural means.

- 50. In addition, Steps (4) and (5) of the above-described GE process must be carried out in a way that produces a transgene composed of multiple genes and other genetic elements that are connected together in a precise way and order. The functionality of transformed plants depends both on the foreign DNA knitted together in the transgene, and the way and order in which the foreign DNA is added to the transgene.
- 51. Furthermore, all of this must be accomplished without disrupting any other important agronomic or nutritional aspects of the plant's physiology or development, without altering functions essential to plant survival such as responses to drought stress, and while also avoiding the creation of any novel proteins or phytochemicals that might be either toxic or allergenic to mammals.

Step 1: Identifying Target Genes

- 52. The genetic engineering process begins with the identification of a functional trait in an organism that might have certain desirable effects if introduced into a specific crop or plant where it does not naturally exist. The two most common genetically engineered traits in corn are herbicide tolerance (as in Roundup Ready corn) and insect resistance (as in *Bt* corn).
- 53. When a potential GE trait is identified, scientists then try to isolate the genes responsible for the trait.

- 54. One common way of accomplishing this task is to make a "map" of the genome using a variety of techniques.
- 55. Unique DNA sequences containing, or near to, the foreign DNA of interest can also be tracked, and are often referred to as "markers" for specific traits.
- 56. Either genetic mapping and/or marker genes can be used to track and identify the gene(s) of interest in the GE process.

Steps 2-3: Isolating and Retrieving the Target Genes

- 57. Once genes of interest are identified and mapped, techniques are used to amplify and identify the genes so they can then be isolated and retrieved.
- 58. A class of enzymes from bacteria called restriction endonucleases (often called "restriction enzymes") is used to cut the donor-organism DNA at specific short sequences, each generally containing four to eight genes, or units.
- 59. Hundreds, or even thousands, of segments of cut or broken donor organism DNA are then attached to easy-to-work-with bacterial DNA, creating what is called a vector.
- 60. A vector is a synthetic construct made in the lab by stitching together the DNA segments of the donor organism with DNA sequences from small bacterial structures called plasmids.

- 61. Vectors are, in essence, artificially engineered bacterial plasmids that are extremely unlikely to occur in nature in the same form as laboratory-produced vectors.
- 62. Because only a relatively small percentage of transformed bacterial cells pick up and express the donor genes of interest, genetic engineers need a way to distinguish the properly transformed cells from the large majority that are not transformed. For this reason, a "selectable marker" gene is included in a vector, allowing the transformed cells to survive when treated with a specific chemical (often an antibiotic), while the non-transformed cells are killed.
- 63. The process of isolating and transferring one or more foreign genes into another organism (bacterial, plant, or others) is called cloning.
- 64. The separate steps within the cloning process, and especially the sequence of steps, have no parallel in nature and are both synthetic and artificial.

Step 4: Modifying the Target Gene for Insertion

65. Once the gene that confers the trait of interest is identified and verified, several more steps must be carried out to assure that the gene functions properly in plants. Modifications may be necessary to assure that the gene turns on at the right time, in the correct part of the plant, and then is expressed strongly enough to confer the desired trait, but not so strongly that other aspects of the plant's physiology or biochemistry are disrupted.

- 66. For example, promoters (the DNA sequences determining when a gene is "turned on") that work in bacteria do not function effectively in plants, and so must be replaced.
- 67. Either a promoter from a plant virus, such as the cauliflower mosaic virus (CaMV S35), or a plant promoter, will be spliced into the transgene, replacing the native bacterial promoter.
- 68. The selection of the appropriate promoter is critical, since different promoters vary in terms of: (a) how strongly they "turn on" the target gene, (b) the tissues of the plant in which they are most likely to function in, (c) the stage of crop development during which they are most likely to be active or inactive, and (d) how the gene will respond to environmental stresses or cues ranging from excessive heat or cold, to insect feeding, exposure to a plant disease, or imbalances in soil nutrients.
- 69. Because the cellular compartments in bacteria differ greatly from those in plant cells, another common modification involves the addition of a DNA sequence that will direct the gene of interest to "turn on" in the desired location in the target plant.
- 70. The genes in foreign DNA are often expressed at lower levels in the target plant than in the donor organism. Therefore, the genetic elements within,

and sequence of these foreign genes, are often altered to increase gene expression through a complex process called "codon optimization".

- 71. Finally, turning a gene off at the right time can be just as important as turning it on. This process primarily involves the addition of the most appropriate combination of promoters and terminators.
- 72. The end result of this process of gene modification, regulation, and codon optimization is what is called a "transgene", or "gene cassette".
- 73. The transgenes used to create today's commercial GE crops all contain multiple, highly modified bacterial genes, stitched together with a variety of marker genes, promoters, and terminator sequences.
- 74. There is no counterpart in nature for these multi-element transgenes, which are synthetic creations resulting from extremely complex genetic recombinations of foreign DNA brought about by humans in a laboratory.

Steps 5-8: Inserting the Gene into the Crop Plant and Confirming Its Expression

- 75. Once the transgene is deemed ready, it must be transferred into the genome of the target plant.
- 76. This transfer is done through an artificial, human-controlled process, because there is no natural way for foreign DNA from several different organisms, knitted together in a precise way and order within a transgene, to get into a plant's genome.

- 77. The target crop cells are usually callus tissue cells, and are generally regarded as the plant equivalent of mammalian stem cells.
- 78. Two methods have been used to move transgenes into target crops, including all commercial GE corn varieties.
- 79. The first involves use of an *Agrobacterium tumefaciens* bacterial vector, and the second uses sheer force, through "microprojectile bombardment" using what is commonly called a "gene gun."
- 80. Agrobacterium tumefaciens bacteria contain a unique kind of plasmid that can naturally inject its DNA into plant cells, as a step in promoting the growth of crown galls on the plant. The crown gall is a mass of undifferentiated plant cells that are an ideal habitat supporting the growth of Agrobacterium tumefaciens bacteria.
- 81. To make use of this unique capability of *Agrobacterium tumefaciens* plasmids, genetic engineers clone the transgene to the plasmid in the laboratory, while also removing genes that are a natural part of the bacterium's plasmid, but might be harmful to the target plant. This makes it possible for the transgene to, in effect, hitch a ride with the now-benign plasmid into the plant's cells.
- 82. Once inside plant cells, the transgene's promoter gene begins to drive expression of the gene, or genes, conferring the desired trait to the target plant.

- 83. The use of a cloned bacterial plasmid to carry a complex, multielement transgene constructed in a laboratory into a target plant's genome could not occur in nature.
- 84. Another approach to move transgenes inside plant cells is the "gene gun" a device for injecting cells of a target plant like corn with genetic information from outside the corn genome.
- 85. While there are several types of gene guns, the following photograph is an example (the PSD-1000/He Particle Delivery System, in this exemplar):



86. Just as in the case of cloned *Agrobacterium tumefaciens* plasmids, there is no counterpart of the gene gun found in nature – it is strictly a man-made device.

- 87. Using this approach, microscopic particles of tungsten or gold are coated with the transgene and are literally shot into the plant cells.
- 88. Both in the case of an *Agrobacterium tumefaciens* plasmid vector and the gene gun, the selectable marker gene that accompanies the transgene of interest is then used to determine which, if any, of the engineered plant cells have taken up and are expressing the transgene.
- 89. Once cells in which the transgene appears to be functioning are isolated, whole plants are regenerated from the cells by adding the appropriate plant hormones to the medium in which the cells are growing.
- 90. Because current GE transformation techniques can result in rearrangements of genes, or transgene insertion at several sites in the crop genome, the now transformed genome is analyzed using a variety of methods to compare actual to expected gene patterns, based on the original map or sequence of the target plant's genes. Transformed events that appear to have possibly detrimental anomalies are dropped from the development process.
- 91. Regenerated, whole plants are also tested to determine whether the gene is functioning as hoped, and without triggering any unexpected physiological or developmental changes. This is accomplished by checking to assure that: (a) the desired trait is expressed (*e.g.*, insect resistance or herbicide tolerance), and (b)

regenerated plants grow normally in a wide range of environments, and perform acceptably despite various biotic and abiotic stresses.

D. These Genetic Engineering Processes Are Inherently Different from Natural Plant Reproduction and Evolution

- 92. Mechanisms and steps similar to those described above have been used in developing all commercially important GE corn varieties grown between 2009-2013.
- 93. Other transformation techniques exist, and more will almost certainly be developed in the future.
- 94. Regardless of the specific methods used to create a given GE corn event, the process relied upon is inherently artificial and unnatural.
- 95. Several of the essential genetic elements are synthetic constructs, pieced together through a carefully sequenced series of gene modifications that entails eliminating some DNA that would undermine performance or add deleterious traits, coupled with adding other genes or genetic elements to enhance a GE corn crop's performance.
- 96. The combination of genetic transformations required to move foreign DNA embodied in a transgene into a plant genome, and then gain its expression and the right amount of expression at the correct time do not occur in nature, despite the fact that specific steps in the genetic engineering process take advantage of "natural" bacterial or viral capabilities.

97. Accordingly, the GE corn plants from which the corn-based ingredients in Kix cereals were derived, are inherently artificial and differ in profound ways from non-engineered corn, and hence are also not natural.

VI. MAJOR TRAITS IN GE CORN: SOURCES, EFFECTS AND PATENTS

- 98. Nearly all GE corn sold by Monsanto since at least 2007 has been covered by some combination of patents issued by the U.S. Patent and Trademark Office ("PTO") on the three most common traits: insect resistance in Monsanto's YieldGard corn with *Bt* protection against the Corn Rootworm, YieldGard corn with *Bt* protection against the European Corn Borer, and herbicide tolerance in Roundup Ready corn 2 (the next generation of Monsanto's original "Roundup Ready" corn).⁶
- 99. The extent of patent coverage for these (and other) GE traits and/or genetically engineered crops is remarkable.
- 100. On average, there are fourteen patents on each of Monsanto's twelve major GE corn products, each of which includes multiple claims regarding specific, novel, synthetic, artificial, unique, and/or non-natural or unnatural aspects of the invention. Each "claim" is a patentable component of the "invention",

⁶ Other biotechnology companies such as Syngenta, DuPont, and Dow hold similar patents on their bioengineered agricultural products as well.

describing a unique step in the genetic engineering process, or some characteristic or attribute of a transformed corn plant.

- 101. As more GE traits are added into a Monsanto corn product, "stacked trait" varieties are created and the number of patents and claims increases. However, the common element remains the same: each trait involves the construction and transfer of multi-element transgenes containing foreign DNA.
- 102. For all of its commercial GE corn crops, Monsanto provides a list of applicable patents (*see* Appendix C; Keenan Decl., Ex. 14).
- 103. A deeper understanding of the uniqueness and unnatural nature of GE plants and the food derived from them can be obtained from a review of the claims made in a subset of the patents awarded for the major GE corn events and traits that have been in the marketplace since 1996.
- 104. These patents confirm, over and over again, the distinction between GE transformation techniques and natural methods of plant genetic evolution and/or plant breeding.
- 105. Each of the genetic elements described would not be found in corn in the absence of genetic engineering. It is impossible that they could find their way into corn, and then impact the corn genome in the same way as is described in these patents.

- 106. Moreover, without genetic engineering, corn exhibiting "stacked traits"—for example, corn that has genes expressing both the Cry1Ab and CP4-EPSPS endotoxins to exhibit insect *and* herbicide resistance would simply never happen in nature without human intervention.
- 107. Narrative descriptions follow of the major traits in selected, key GE corn crops, including references to some of the patents underlying each trait.

A. <u>Insect Resistance</u>

- 108. For decades, a common goal of plant breeders has been developing crop varieties that are naturally tolerant of pest attacks, or somehow better able to overcome the impact of pests. A key motivation driving such breeding work has been to reduce the farmer's need to apply and pay for pesticides.
- 109. In the mid-1990s, the *Bt* trait was created to control insect pests through genetic engineering, so that GE corn would exhibit traits that repelled or killed pests, thereby reducing agriculture's dependence on conventional insecticides that are sprayed on corn in a liquid form, or worked into the soil in a granular form.
- 110. Two important *Bt* technologies found in Monsanto's "YieldGard" corn products and subsequent progeny remain among the top three traits incorporated into GE corn. They are the primary technologies used to protect corn

plants from insect feeding damage. Other leading GE-seed companies have developed and now market similar, *Bt*-based, insect-protected corn hybrids.

a. <u>Corn Borer Bt Technology</u>

- 111. In 1997, corn containing the Cry1Ab protein (an insect toxin) from one type of the soil bacterium *Bacillus thuringiensis* (*Bt*) was introduced through genetic engineering. This "corn borer" *Bt* trait was created to control Lepidoptera (moth) pests, mainly the European corn borer, and, secondarily, the corn earworm.
- 112. In addition to its bacterial origin, the Cry1Ab endotoxin is expressed (turned on) by a promoter (called PE-35S) extracted from the Cauliflower Mosaic Virus ("CaMV"), and then inserted (spliced) in the lab in front of the bacterial genes expressing the Cry1Ab endotoxin.⁷
- 113. This viral promoter is rarely found in plant genomes (genetic material) in the wild. Instead, in the field of genetic engineering, it is manipulated in the lab to enhance the expression (increase the production) of the Cry1Ab protein, or other proteins or endotoxins of interest to genetic engineers.

⁷ The opposite of a promoter—a terminator—must also be used to stop the process of copying (transcribing) the protein. At the end of the Cry1Ab endotoxin, the transcription terminator NOS 3' is inserted, which comes from a different bacterium than the Cry1Ab protein (*Agrobacterium tumefaciens*).

- 114. The goal of this GE process is to produce larger amounts of the toxin in plant tissues rendering the genetically engineered corn more resistant to insects.
- 115. This technology is man-made, synthetic, and covered by several patents.
- 116. Monsanto lists U.S. Patent No. 6,180,774 as one of the patents covering YieldGard Corn Borer corn, varieties that express the corn borer *Bt* technology. The title of the patent is: "*Synthetic DNA* sequences having enhanced expression in monocotyledonous plants and method for preparation thereof." (Emphasis added).
- 117. The patent emphasizes the critical difference between YieldGard Corn Borer Corn and natural corn: "The present invention provides novel synthetic DNA sequences, encoding a polypeptide or protein that is not native to a monocotyledonous plant, that is expressed at greater levels in the plant than the native DNA sequence if expressed in the plant."
 - 118. The word "synthetic" appears in the patent 29 times.

b. <u>b. Rootworm *Bt* Technology</u>

119. Later variations in *Bt* corn technology became even more sophisticated.

- 120. The "rootworm" *Bt* trait was developed to produce the Cry3Bb1 endotoxin in the cells of corn plants (and especially their roots) to control the larvae of corn rootworm beetles and certain other soil-dwelling insects. This variation on *Bt* technology produces a toxin that is targeted at juvenile insects in particular aiming to control them at a life stage when they are far more sensitive to *Bt* endotoxins, and before they have a chance to feed on and damage the roots of corn plants.⁸
- 121. In this transgene, a sequence from a wheat gene that enhances transcription is spliced after the promoter, but before the Cry3Bb1 protein.
- 122. Wheat, like corn, is a grass, but is not sufficiently close to corn to allow successful pollination between these crops in the absence of genetic engineering.
- 123. So, in nature or in commercial varieties of wheat and corn bred through conventional, non-GE techniques, a wheat genetic element would never be found in corn, and *vice versa*.

⁸ The Cry3Bb1 protein is not found in plants without using genetic engineering. Like the Cry1Ab gene, this technology also relies on the Cauliflower Mosaic Virus "CaMV") to promote expression of the protein, although it comes from a different gene of that virus. A terminator is also used.

- 124. Each of these alterations alone would be extremely rare occurrences in nature, and for all them to happen in combination, in the right sequence and to the same degree as in a GE crop, is impossible without genetic engineering.
- 125. Like corn borer *Bt* technology, rootworm *Bt* technology is man-made, synthetic, and covered by several patents.
- 126. U.S. Patent No. 6,501,009 covers Monsanto's YieldGard Rootworm corn. The invention is described as providing "for *transgenic plants* which have been *transformed with a DNA construct or expression cassette* of the present invention that is expressed and translated at unexpectedly high levels by the plant which results in surprisingly high levels of delta.-endotoxin accumulation." ('009 Patent, col. 7) (emphasis added).
- 127. Six of the DNA sequences disclosed in the patent are described as "synthetic." Several of the sequences also contain the characterization "Artificial Sequence," and some are described as "synthetic" or a "non-naturally occurring amino acid sequence." (Emphasis added).
- 128. Another patent underlying this technology, U.S. Patent No. 6,063,597, was granted on May 6, 2000 and covers YieldGard rootworm corn expressing the Cry 3Bb1 *Bt* endotoxin. The patent discloses "novel methods for constructing *synthetic* Cry3* proteins, *synthetically*-modified nucleic acid sequences encoding

such proteins, and compositions arising therefrom." ('597 Patent col.7 (emphasis added).)

- 129. This patent describes multiple alterations made to the natural Cry3Bb endotoxin. The changes include "at least one amino acid substitution, one amino acid addition, or one amino acid deletion in the primary sequence of the native or unmodified Cry3Bb polypeptide" (*Id.* col.793).
- 130. Another patent, U.S. Patent No. 7,250,501, was issued to a team of Monsanto scientists on July 31, 2007 and covers the genes expressing two additional *Bt* endotoxins for control of the corn rootworm (derived from Cry1A and Cry1F). This patent includes 16 claims and the Abstract begins with this sentence: "Disclosed are novel *synthetically-modified B. thuringiensis* chimeric crystal proteins having improved insecticidal activity against coleopteran, dipteran and lepidopteran insects." ('501 Patent, Abstract) (Emphasis added).
- 131. As used to describe the invention covered by U.S. patent No. 7,250,501, the term "*chimeric*" means that the synthetic *B. thuringiensis* proteins were derived from two different organisms, before that foreign transgenic gene was inserted into the corn genome.

B. <u>Herbicide Resistance</u>

132. In 1996, Monsanto introduced a genetically engineered corn that was resistant to glyphosate, the active ingredient in its herbicide "Roundup". The

invention was hugely significant in the field of genetically engineered agriculture: most of the acreage planted to GE crops since 1996 have included the so-called "Roundup Ready" gene.

- 133. Transformation with this gene renders the resulting crops insensitive to broad-spectrum, glyphosate-based herbicides ("GBH") such as Roundup. As a result, farmers can spray Roundup on so-called "Roundup Ready" GE corn varieties without harming the corn, but killing all or most of the weeds in the field.
- 134. The CP4-EPSPS protein that confers resistance to the herbicide glyphosate came from the bacterium *Agrobacterium tumefaciens*.
- 135. The CP4-EPSPS protein has been spliced to the same Cauliflower Mosaic Virus ("CaMV") promoter as the Cry1Ab endotoxin, and uses the same NOS 3' terminator.
- 136. As in the case of the Cry1Ab endotoxin, it would be extremely unlikely that the bacterial EPSPS gene would end up in corn, and similarly unlikely that any of the other essential genetic elements required to express and regulate the gene would also be present in the same corn plants.
- 137. A review of major patents covering glyphosate-resistance technology adds further evidence supporting the inherent distinctions between GE transformation techniques and natural methods of plant genetic evolution.

a. Roundup Ready Corn

- 138. Monsanto's original Roundup Ready (glyphosate resistant) corn was protected by U.S. Patent No. 6,040,497, among others.
- 139. Patent 6,040, 497 states: "The plants of the current invention have a mutant EPSPS gene which confers glyphosate resistance." In fact, "[t]wo mutations were introduced into the amino acid sequence of EPSPS to confer glyphosate resistance."
- 140. Patent 6,040,497 includes five DNA sequences described as "artificial." The "header" information for sequences 2, 3 and 4 includes the following statement: "ORGANISM: Artificial Sequence."

b. Roundup Ready Corn 2

- 141. By 2009, Monsanto was selling very little corn with the original Roundup Ready trait it had begun to implement the next generation of its glyphosate-resistant Roundup Ready technology, called "RR Corn 2", which now appears in almost all GE corn planted in the United States.
- 142. Monsanto received U.S. Patent No. 7,582,434 B2 on September 1, 2009, one of the key patents protecting "RR Corn 2." In the "SUMMARY OF THE INVENTION" section of that patent, the process of creating the Roundup

⁹ A later patent explains that "GA21 contains at least 3 transgene expression cassettes arranged in tandem in the genome of GA21 event." (Patent 6,825,400).

Ready Corn 2 event PV-ZMGT32(nk603) is described. Two transgene cassettes were involved.

- 143. The first transgene cassette was composed of a rice actin 1 promoter and a rice actin 1 intron "operably joined" to a *Arabidopsis* (a plant) chloroplast transit peptide sequence, which is in turn "operably connected" to the EPSPS gene from *Agrobacterium tumefaciens*, which is also "operably connected" to a NOS 3' transcriptional terminator from another bacterium. ('434 Patent, col. 2).
- 144. The second transgene cassette uses a Cauliflower Mosaic Virus promoter (CaMV 35S), "operably connected" to the *Arabidopsis* chloroplast transit peptide, and then joined with the EPSP gene from *Agrobacterium tumefaciens*, and the same NOS terminator. (*Id.*)
- 145. Accordingly, in developing corn event PV-ZMGT32(nk603), Monsanto drew upon and knitted together four genes from plants not sexually compatible with corn, four bacterial genes, and one gene from a virus.
- 146. Another Monsanto patent covering Roundup Ready 2 crops is U.S. Patent No. RE39,247E, covering the mutated EPSPS enzyme that results in glyphosate resistance.
- 147. In the "BACKGROUND OF THE INVENTION" section of that patent, it states that: "[r]ecent advances in genetic engineering have provided the

requisite tools to transform plants to contain *foreign* genes." ('247 Patent, col. 1) (emphasis added).

148. The patent uses the word "natural" to distinguish the un-mutated EPSPS enzyme existing in nature from the mutated version produced by the patented gene:

"In general, while such natural tolerance [to glyphosate] has been reported [in bacteria], there is no report suggesting the kinetic superiority of the naturally occurring bacterial phosphosate-tolerant EPSPS enzymes over those of mutated EPSPS enzymes nor have any of the genes been characterized. Similarly, there are no reports on the expression of naturally glyphosate-tolerant EPSPS enzymes in plants to confer glyphosate tolerance."

(*Id.* at col. 2).

- 149. The RR Corn 2 patent explains that genes from five different bacteria were used to code for the more kinetically efficient strain of EPSPS enzymes (called Class II EPSPS). These strains, in turn, were derived from seven bacterial sources.
- 150. Twenty-five (25) separate DNA sequences in Patent RE39,247 are described as both "artificial" and "synthetic". A total of 149 claims are made in this patent.

VII. <u>CONCLUSION</u>

151. Accordingly, based on my knowledge of genetic engineering, the U.S. corn market and supply chains for corn-derived ingredients between 2009-2013, and information provided to Plaintiffs by General Mills concerning the company's

purchases of corn ingredients, I conclude that the majority of the corn used to make

Kix was genetically engineered (GE) corn, created through complex, multi-step

processes conducted by humans that have no counterpart in nature. The corn used

to make Kix cereal has, and still contains, synthetic transgenic DNA that will never

be replicated in the natural world without human intervention.

152. This declaration is based upon the information and data presently

available to me. I understand that additional, different, and/or updated data may be

made available to me in advance of trial. I, therefore, reserve the right to amend or

modify my testimony.

VIII. <u>VERIFICATION</u>

I declare under penalty of perjury of the laws of the United States that the

foregoing is true and correct to the best of my knowledge, information, and belief,

and that this declaration was executed at Enterprise, Oregon, this 19th day of June,

2015.

Charles M. Benbrook

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Appendix A. Resume

CHARLES M. BENBROOK

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EDUCATION

B.A. Degree - Economics, Harvard University (1971)

M.A. Degree - Agricultural Economics, University of Wisconsin (1979)

Ph.D.Degree - Agricultural Economics, University of Wisconsin (1980)

EMPLOYMENT HISTORY

Washington State University, Center for Sustaining Agriculture and Natural Resources, Research Professor. August 16, 2012 to May 15, 2015.

Research scientists and program leader for the "Measure to Manage Program – Farm and Food Diagnostics for Sustainability and Health."

The Organic Center, Chief Scientist. January 1, 2006 to May 31, 2012.

Developed and managed a program of research on the environmental and consumer health benefits of organic foods and farming. Responsible for synthesizing new research and science on the impacts of organic and conventional farming systems and regulation on food safety, nutritional quality, the economic performance of the organic sector.

<u>Benbrook Consultant Services (BCS)</u>. Sole proprietor of a Troy, Oregon based consulting business. December 1, 1990 to present.

Services for domestic and international clients in the public and private sectors. Major areas of focus include biotechnology; pesticide use, risks, and regulation; adoption and costs-benefits of Integrated Pest Management; impacts of federal environmental and food laws, especially the Food Quality Protection Act of 1996 and Federal Food, Drug, and Cosmetic Act. BCS specializes in the development of novel methodologies to assess environmental and public health risks and issues, and makes heavy use of government data sets in policy analysis.

Clients include national consumer and environmental groups, international organizations, companies, federal and state government agencies, trade associations, and academic research organizations. Benbrook has also served as an expert witness in several pesticide and biotechnology related lawsuits.

<u>National Research Council/National Academy of Sciences</u>, Washington, D.C. Executive Director, Board on Agriculture. January 16, 1984 to November 30, 1990.

The Board on Agriculture was one of eight major units of the NRC. The executive director is responsible for overseeing and managing activities of the Board. When hired, the Board had three staff (a secretary and two program officers). Benbrook expanded the scope of activities and raised over \$1 million per year. The staff grew over seven years to exceed 20.

Major NAS reports carried out during this period covered the early methods and applications of agricultural biotechnology; unique risks faced by infants and children from pesticide exposure, modernizing U.S. pesticide regulatory law, pesticide use and resistance, options to improve the nutritional composition of animal products, animal nutrition needs, agricultural education programs at the federal level, soil and water conservation, germplasm conservation and use, the healthfulness of food products and options to improve food safety, agriculture's impact on water and soil quality, and agricultural research and sustainable development needs and challenges.

<u>Subcommittee on Department Operations, Research, and Foreign Agriculture, Committee on Agriculture, U.S. House of Representatives</u>. Subcommittee chaired by Congressman George E. Brown, Jr., Staff Director. April 1981 - January 13, 1984.

Responsibilities of the staff director included: (i) preparing and analyzing legislation within the jurisdiction of the subcommittee (agricultural research

system, pesticide regulation, foreign agricultural issues and programs, and plant and animal protection programs); (ii) conducting subcommittee business meetings; (iii) briefing members and staff on legislation and oversight activities; and (iv) analyzing annual budget proposals.

During this period, Benbrook participated in the drafting and passage of legislation in many areas. Major pesticide reform legislation was debated each year, but never passed. Benbrook and staff working for Congressman Jim Weaver of Oregon drafted the first version of what became the Organic Food Production Act (passed in the 1990 farm bill). Oversight hearings by the Subcommittee on pesticide risk and regulatory issues led to the recognition, and ultimately the resolution of the Delaney paradox (the focus on a 1987 NAS report, see below).

<u>Council on Environmental Quality, Executive Office of the President, Agricultural Policy Analyst.</u> December 1979 - March 1981.

Responsibilities included: (i) representing CEQ on various Executive Branch committees; (ii) analyzing natural resource data and policy options; (iii) preparing the agricultural section of the Natural Resources chapter in CEQ's 1980 annual report; and (iv) principal author of the Final Report to the President of the National Agricultural Lands Study.

AWARDS and HONORS

Excellence in Science Award, OTA/TOC Dinner, March 2014.

Appointed as member, USDA's AC 21 agricultural biotechnology advisory committee, 2010, and reappointed in 2013.

Appointed to AGree Advisory Committee, 2010.

Appointed as Adjunct Faculty Member, Department of Crop and Soil Sciences, Washington State University, Pullman, Washington, 2007.

Graduated cum laude from Harvard University, 1971.

Received \$1,000 cash award from the Council on Environmental Quality for contributions to the completion of the National Agricultural Lands Study.

RESEARCH and ANALYTICAL ACTIVITIES

1979-1983: Carried out the basic analytical work on the extent and distribution of soil erosion that was used in developing and building the case for the conservation provisions in the 1985 farm bill. This work, carried out with the help of Dr. William Larson, Univ. of Minnesota, was the first independent analysis of erosion challenges conducted outside USDA utilizing the Natural Resources Inventory dataset. The results were reported in several publications (see list below), as well as in CEQ publications and the 1983 American Farmland Trust report on soil conservation. These analytical findings were cited by all major participants in the debate leading to passage of Title 12 in the 1985 Food Security Act.

1981- present: Carried out Congressional oversight investigation of the pesticide regulatory activities of the Environmental Protection Agency, focusing on Reaganadministration policy changes. Wrote the synthesis volume and compiled the other three volumes of the subcommittee report: "EPA Pesticide Regulatory Study." This report contained a comprehensive review of the legal, administrative, and scientific dilemmas confronting pesticide regulatory officials. The report's findings and recommendations formed the basis of several major legislative proposals to amend the Federal Insecticide, Fungicide, and Rodenticide Act in the 99th-101st Congresses, and led to the 1984-1987 NAS/NRC project that produced the report *Regulating Pesticides in Food: The Delaney Paradox* (1987). This NAS/NRC report identified the need for further assessment of the unique regulatory challenges entailed in protecting the health of infants and children, and the NAS/NRC project that produced the seminal 1993 report *Pesticides in the Diets of Infants and Children*.

The recommendations in the 1993 NAS/NRC report were adopted fully in the 1996 "Food Quality Protection Act." From 1997-2006, Benbrook carried out many studies of FQPA implementation for Consumers Union and other clients. Multiple books, reports, and articles were developed reporting this work.

Benbrook has remained actively involved in the developing methods to assess pesticide residue and risk levels in food. In 2005-2006, the EPA's Office of Inspector General hired Benbrook to apply his risk model to an evaluation of the impacts of the Food Quality Protection Act (FQPA).

1984-present: Helped design, develop and apply the dataset and analytical methodology underlying the work of the NAS/NRC committee on pesticide residues in the food supply. In conjunction with Dr. John Wargo of Yale

University and Mr. Richard Wiles of the Board on Agriculture staff, developed the method used by the NAS/NRC committee to conduct a cumulative risk assessment of exposure and risks to oncogenic pesticides, the first such analysis ever conducted. The method utilized USDA food consumption data, and EPA tolerance and toxicological data, and a Monte Carlo simulation model. The basic method set forth in this report formed the foundation for contemporary EPA cumulative risk assessments of the organophosphate insecticides.

1988-1989: Compiled data and conducted analysis of private sector research investments in the food and agricultural industries. The results of this analysis are reported in Appendix B, "Private Sector Research Activities and Prospects", in *Investing in Research: A Proposal to Strengthen the Agricultural, Food, and Environmental System*, NAS Press, 1989.

1995-present: Developed the first system in the U.S. designed to quantify the level of adoption of Integrated Pest Management along the "IPM continuum." The original Benbrook Consulting Services IPM measurement system was set forth in Chapter 7 in the Consumers Union book *Pest Management at the Crossroads* (1996). The first empirical application focused on weed management in corn and soybeans and was done as part of a World Wildlife Fund project. The results were reported in a presentation made to the Weed Science Society of America circa 1998.

This early model of IPM adoption has been refined and augmented through several iterations and applications in projects with the Wisconsin Potato and Vegetable Growers Association and University of Wisconsin-Madison, Gerber Products Company, Glades Crop Care of Jupiter Florida, and the Lodi-Woodbridge Wine Grape Commission. The pesticide risk indicator component of the IPM measurement system is now the "Pesticide Environmental Assessment System," or PEAS. In 2007, a large team led by Dr. Tom Green of the IPM Institute, applied for and received an \$800,000.00 NRCS Conservation Innovation Technology grant to refine the water quality components in PEAS and make the model accessible via the Internet. Benbrook is a PI on this grant. Benbrook wrote an earlier, successful RAMP grant proposal (Risk Avoidance and Management Program, an USDA competitive grant program focusing on large, multistate IPM projects) that provided support for enhancement of modules in PEAS.

1999-2004: Developed and applied a method to estimate the usage of subtherapeutic doses of antimicrobials in livestock for growth promotion and disease prevention, as part of projects focusing on antibiotic resistance management. Developed the model and results reported in the Union of

Concerned Scientists' report *Hoggin It! Estimates of Antimicrbial Abuse in Livestock* (2001). Subsequent work has focused on the costs and prevention of antibiotic resistance.

2004-June 2012: Through work with The Organic Center, Benbrook is developing a food quality index modeling system encompassing positive (*e.g.*, nutrient density, nutrient composition, taste) and negative attributes of food (*e.g.*, fat, salt, sugar levels; pesticide residues/risk; bacteria and mycotoxins). An Access database and modeling system has been developed to assess differences in the nutrient density of foods produced using conventional and organic production systems.

REPORTS, ARTICLES, AND PRESENTATIONS

Benbrook has published peer reviewed articles in multiple disciplines including agricultural biotechnology, pesticide use and residues in food, soil and water conservation, pesticide risk assessment methods, Integrated Pest Management, germplasm conservation, scientific basis for evaluating agricultural technologies, antibiotic use and resistance, food safety, international agricultural development, sustainable agriculture, and agricultural policy.

Peer Reviewed Articles

Marcin Baranski, Dominka Srednicka-Tober, Nikolaos Volakakis, Chris Seal, Roy Sanderson, Gavin B. Stewart, Charles Benbrook, Bruno Biavati, Emilia Markellou, Charilaos Giotis, Joanna Gromadzka-Ostrowska, Ewa Rembiałkowska, Krystyna Skwarło-Son, Raija Tahvonen, Dagmar Janovska, Urs Niggli, Philippe Nicot and Carlo Leifert, "Higher antioxidant and lower cadmium concentrations and lower incidence of pesticide residues in organically grown crops: a systematic literature review and meta-analyses," *British Journal of Nutrition*, July 15, 2014, http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=928-9221&fulltextType=RA&fileId=S0007114514001366>

Charles M. Benbrook, Gillian Butler, Maged A. Latif, Carlo Leifert, and Donald R. Davis. 2013. "Organic Production Enhances Milk Nutritional Quality by Shifting Fatty Acid Composition: A United States-Wide, 18-Month Study," PLOS ONE, December 9, 2013 http://dx.plos.org/10.1371/journal.pone.0082429 >

Charles M. Benbrook and Brian P. Baker, "Perspective on Dietary Risk Assessment of Pesticide Residues in Organic Food," *Sustainability* 2014, 6(6),

3552-3570; doi:10.3390/su6063552

Benbrook, C.M. 2013. IMPACTS OF CHANGING PEST MANAGEMENT SYSTEMS AND ORGANIC PRODUCTION ON TREE FRUIT PESTICIDE RESIDUES AND RISK. Acta Hort. (ISHS) 1001:91-102, http://www.actahort.org/books/1001/1001 8.htm

Benbrook, C. Impacts of Genetically Engineered Crops on Pesticide Use in the U.S. – the First Sixteen Years, *Environmental Sciences-Europe*, 24:24 (2012)

Benbrook, C. Inappropriate measures of pesticide health risks, Letter to the Editor, *The Annals of Internal Medicine*, posted September 21, 2012

Benbrook, C. "The Impacts of Yield on Nutritional Quality: Lessons from Organic Farming," *HortScience*, (2007).

McCullum, C., C.M. Benbrook, L. Knowles, S. Roberts, T. Schryver, "Application of Modern Biotechnology to Food and Agriculture: Food Systems Perspective", J. Nutr. Educ Behav., (2003); 35:319.

Benbrook, C. et. al. "Use of 'resistance risk profiles' to guide resistance management planning", *Pesticide Outlook*, 14:3, June 2003.

Baker, B. P., Benbrook, C. M., Groth, E., and K.L. Benbrook. "Pesticide residues in conventional, integrated pest management (IPM)-grown and organic foods: insights from three US data sets." *Food Addit. Contam* 19.5 (2002): 427-46.

Benbrook, C. M. et al. "Developing a pesticide risk assessment tool to monitor progress in reducing reliance on high-risk pesticides." *American Journal of Potato Research*, 79 (2002): 183-99.

Benbrook, C. M. "Organochlorine residues pose surprisingly high dietary risks." *J Epidemiol Community Health* 56.11 (2002): 822-23.

Benbrook, C. "Do GM Crops Mean Less Pesticide Use?", *Pesticide Outlook*, Royal Society of Chemistry, October 2001.

Benbrook, C. M. "Performance criteria for IPM: measuring IPM results," Henk, M. Kogan M. IPM in Oregon: Achievements and Future Directions, Special Report 1020, 19-27. 2000. Corvallis: Integrated Plant Protection Center, Oregon State

University Extension Service.

Benbrook, C. "Apples, Kids and Core Science," *Choices*, Third Quarter 2000, Am. Ag. Econ. Assoc.

Lynch, S., D. Sexson, C.M. Benbrook, M. Carter, J. Wyman, P. Nowak, J. Barzen, S. Diercks, J. Wallendal, "Working out the Bugs", *Choices*, Third Quarter 2000, Am. Ag. Econ. Assoc.

Benbrook, C. "Carcinogen Policy at EPA," *Science*, Vol. 219, No. 4586: 798. February 18, 1983.

Benbrook, C. "What We Know, Don't Know, and Need to Know About Pesticide Residues in Food," January 23, 1990. Chapter 15 in *Pesticide Residues and Food Safety: A Harvest of Viewpoints*, Edited by B.G. Tweedy, et. al., Amer. Chemical Society Symposium Series # 446, 1991.

Benbrook, C. "Why A Leopold Center for Sustainable Agriculture?," February 6, 1990. Jan-Feb. 1991 issue of the *Journal of Soil and Water Conservation*.

Benbrook, C., and Moses, P. "Engineering Crops to Resist Herbicides," *Technology Review*, MIT Press, November-December 1986, pp. 55-61, 79.

Benbrook, C. "Is American Environmental Policy Ready for de Minimis Risks in Water?", *Regulatory Toxicology and Pharmacology* 8, pp. 300-307 (1988).

Benbrook, C. "First Principles: The Definition of Highly Erodible Land and Tolerable Soil Loss, *Journal of Soil and Water Conservation*, January-February 1988, pp. 35-38.

Benbrook, C. "The Science and Art of Conservation Policy," *Journal of Soil and Water Conservation*, September-October 1986, pp. 285-291.

Reports, Papers, and Book Chapters (partial list)

Benbrook, C. *Transforming Jane Doe's Diet*, Critical Issue Report, The Organic Center, Boulder, CO., 2011, access at – http://www.organic-center.org/science.nutri.php?action=view&report_id=190

Benbrook, C. The Organic Center's "Dietary Risk Index " - Tracking Relative

Pesticide Risks in Foods and Beverages, The Organic Center, Boulder, CO., 2011, access at www.organic-center.org/DRI

Benbrook, C., and D.R. Davis. *Identifying Smart Food Choices on the Path to Healthier Diets: Documentation and Applications of TOC-NQI, Version 1.1.* The Organic Center, Boulder, CO., 2011, access at: www.organic-center.org/TOC-NQI

Benbrook, C. et al. *A Dairy Farm's Footprint: Evaluating the Impacts of Organic and Conventional Dairy Production Systems*, Critical Issue Report, The Organic Center, Boulder, Co., 2010, access at –

http://www.organic-

center.org/science.environment.php?action=view&report_id=184

Benbrook, C. What Does Sustainable Agriculture Have to Offer? Conclusions and Recommendations in Two NAS Reports, Critical Issue Report, The Organic Center, Boulder, Co., 2010, access at – http://www.organic-center.org/science.environment.php?action=view&report_id=180

McCullum-Gomez, C., Benbrook, C., and R. Theuer. *That First Step: Organic Food and a Healthier Future*, Critical Issue Report, The Organic Center, Boulder, CO., 2009, access at http://www.organic-center.org/science.healthy.php?action=view&report_id=149

C., Benbrook, C., X. Zhao, J. Yanez et al. *New Evidence Confirms the Nutritional Superiority of Plant-Based Organic Foods*, State of Science review, The Organic Center, Boulder, CO., 2008, access at -- http://www.organic-center.org/science.nutri.php?action=view&report_id=145

Benbrook, C. *Simplifying the Pesticide Risk Equation: The Organic Option*, Critical Issue Report, The Organic Center, Boulder, Co., 2008, access at http://www.organic-center.org/science.pest.php?action=view&report_id=125

Benbrook, C. "Principles Governing the Long-Run Risks, Benefits, and Costs of Agricultural Biotechnology," Chapter 11, *Biodiversity and the Law: Intellectual Property, Biotechnology, and Traditional Knowledge*. Edited by Charles McManis, Earthscan, 2007.

Benbrook, C. *Unfinished Business: Preventing E. coli O157 Outbreaks in Leafy Greens*, Critical Issue Report, The Organic Center, 2007. 21 pages.

Benbrook, C., Greene, Al., Lu, C., and Landrigan, P. *Successes and Lost Opportunities to Reduce Children's Exposure to Pesticides Since the Mid-1990s*, Critical Issue Report, The Organic Center, 2006. 41 pages.

Benbrook, C. E. coli – Frequently Asked Questions, Critical Issue Report, The Organic Center, 2006. 30 pages.

Benbrook, C. Breaking the Mold – Impacts of Organic and Conventional Farming Systems on Mycotoxins in Food and Livestock Feed, State of Science Review, The Organic Center, 2005. 70 pages.

Benbrook, C. *Elevating Antioxidant Levels in Food through Organic Farming and Food Processing*, State of Science Review, The Organic Center, 2005. 78 pages.

Benbrook, C. "Tracking the Impacts of the FQPA on Pesticide Dietary Risks -- A Preliminary Assessment," report commissioned by the EPA Office of Inspector General, 2005.

Benbrook, C. *Minimizing Pesticide Dietary Exposure Through the Consumption of Organic Food*, State of Science Review, The Organic Center, 2004. 63 pages.

Benbrook, C. "Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Thirteen Years," Critical Issue Report, The Organic Center, 2009.

Benbrook, C. "Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Eight Years". 2003.

Benbrook, C. "Genetically Engineered Crops and Pesticide Use in the United States: The First Nine Years," Ag BioTech InfoNet Technical Paper #7, 2005.

Mellon, M., Benbrook, C., and K.L. Benbrook. *Hogging It!: Estimates of Antimicrobial Abuse in Livestock*, Published by the Union of Concerned Scientists, January 2001.

Benbrook, C. et al. "Update: Pesticides in Children's Foods, An analysis of 1998 USDA PDP

Data on Pesticide Residues," Consumers Union of the U.S., Inc. May 2000.

Benbrook, C., Groth, E., Hanson, M., and S. Marquardt. *Pest Management at the Crossroads*, Consumers Union, 1996. 272 pages.

Benbrook, C. et al. "Do You Know What You Are Eating?" Consumers Union of U.S., Inc. Public Service Projects Department, Technical Division, February 1999.

Benbrook, C., and Marquardt, D. *Challenge and Change: A Progressive Approach to Pesticide Regulation in California*, Cal-EPA, Department of Pesticide Regulation, 1993. 153 pages.

Benbrook, C. "The Road from Rio: An International Policy and Action Framework for Sustainable Agriculture and Rural Development," (Client: FAO/UN), 1994.

Benbrook, C. "U.S. Foreign Aid: What Counts for Sustainable Development?," (Client: Coalition of NGO/PVO groups led by Bread for the World), 1995.

Benbrook, C. "Unraveling Delaney's Paradox: Challenges for the 102nd Congress,"

(Client: Institute for Science in Society).

Benbrook, C. "Costs and Benefits of Water Quality Best Management Practices," (Client: Environmental Protection Agency).

Benbrook, C. "Sustainable Agriculture in the 21st Century: Will the Grass Be Greener?," (Client: Humane Society of the United States), 1992.

Benbrook, C. "Natural Resources Assessment and Policy," Chapter 12 in *Soil Management for Sustainability*, Edited by R. Lal, and F.J. Pierce. Proceedings of a Special Symposium held in Edmonton, Alberta, August, 1989 honoring the work and accomplishments of Dr. William E. Larson.

Benbrook, C. Appendix B, "Private Sector Research Activities and Prospects", in *Investing in Research: A Proposal to Strengthen the Agricultural, Food, and Environmental System*, NAS Press, 1989.

Benbrook, C., and Brown, W. "Public Policies and Institutions to Enhance Crop Productivity," *Crop Productivity Research Imperatives Revisited*, proceedings of the Crop Productivity Revisited Conference, December 11-13, 1985, Airlie, Virginia, pp. 239-257.

Presentations, Comments, Congressional Testimony, and Opinion Pieces

Benbrook delivers between 10 and 20 presentations per year; a partial listing follows.

Benbrook, C. "Private Sector Initiatives to Reduce Children's Pesticide Exposures," AAAS annual meeting symposium on reducing children's pesticide risks, February 19, 2006, St. Louis, Missouri.

Landrigan, P., and Benbrook, C. "Impacts of the Food Quality Protection Act on Children's Exposures to Pesticides," AAAS annual meeting symposium on reducing children's pesticide risks, February 19, 2006, St. Louis, Missouri.

Benbrook, C. "Sowing the Seeds of Destruction," Op-Ed in the New York Times, July 11, 2003. Accessible at http://www.biotech-info.net/sowing_seeds_NYT.html

Benbrook, C. "Stakeholder Roles in Resistance management – Time to Get with the Program" CAST Resistance Management Symposium, April, 2003.

Benbrook, C.M., "Why pesticide risks matter and pose tough challenges for ecolabel programs", In Proceedings of a Conference on Ecolabels and the Greening of the Food Market, Tufts University, Boston MA, November 7-9, 2003.

Benbrook, C., and E. Groth. "Who Controls and Who Benefits from Plant Genomics?," AAAS Genomics Seminar Paper, February 19, 2000.

Nigh, R., Benbrook, C., Brush, S., Garcia-Barrios, L., Ortega-Paczka, R., Perales, H.R. "Transgenic crops: a cautionary tale," Science, Vol. 287 (5460), 2000. Page 1927.

Benbrook, C. M.." Performance criteria for IPM: measuring IPM results," Henk, M. Kogan M. IPM in Oregon: Achievements and Future Directions, Special Report 1020, 19-27. 2000. Corvallis: Integrated Plant Protection Center, Oregon State University Extension Service.

1998-2002 comments to the EPA and reports on the implementation of the Food Quality Protection Act are accessible through the Consumers Union FQPA website at http://www.ecologic-ipm.net.

Benbrook, C. and J. Cook.. "Striving Toward Sustainability: A Framework to Guide On-Farm Innovation, Research, and Policy Analysis," March 2, 1990. Paper presented at the 1990 Pacific Northwest Symposium on Sustainable Agriculture, Vancouver, Washington.

Benbrook, C. "Conflict or Cooperation: The Path to a 1990 Farm Bill," March 22, 1990. Speech presented before the "Who's Writing the Farm Bill?" Conference, sponsored by Governor George Mickelson and the South Dakota Department of Agriculture, Sioux Falls.

Benbrook, C., and Moses, P. "Herbicide Resistance: Environmental and Economic Issues," Proceedings, BioExpo 1986.

Agriculture and Groundwater Quality: Policy Implications and Choices. January 17, 1989. Paper presented as part of the "Technical Session on Agriculture and Groundwater Quality," 1989 Annual Meeting of the American Association for the Advancement of Science, San Francisco, California.

Practical Realities and Political Options in Overcoming World Hunger. February 28, 1989. Invited testimony before the Subcommittee on Natural Resources, Agriculture Research, and the Environment, House Committee on Science and Technology.

Sustainable Agriculture: Policy Options and Prospects. February 28, 1989. Speech before the Institute for Alternative Agriculture Symposium on Sustainable Agriculture, Washington, DC. Published in the American Journal of Alternative Agriculture 4:3-4, pp. 153-159.

Coping With Delaney's Paradox. May 15, 1989. Invited testimony before the Subcommittee on Toxic Substances, Environmental Oversight, Research and Development of the Senate Committee on Environment and Public Works.

Will S. 7222 Unravel Delaney's Paradox? June 6, 1989. Invited testimony before the Senate Labor and Human Resources Committee's Food Safety Hearing.

Priority Setting Mechanisms Utilized by the U.S. Department of Agriculture. June 20, 1989. Testimony before the Senate Agriculture Committee's Agricultural Research and General Legislation Subcommittee.

The United States' Progress Toward Sustainable Resource Development. July 31, 1989. Paper presented at the Forty-fourth Annual Meeting of the Soil and Water Conservation Society, Edmonton, Alberta, Canada.

Balancing Agricultural Production and Resource Conservation Goals Through Commodity Program Reform: Recommendations from the NAS Report Alternative Agriculture. September 21, 1989. Invited testimony before the Senate Committee on Agriculture, Nutrition, and Forestry's Subcommittee on Agriculture Production and Stabilization.

Alternatives to Pesticides: Findings and Recommendations from the NAS Report Alternative Agriculture. September 22, 1989. Invited testimony by Dr. Charles M. Benbrook and Dr. Robert M. Goodman before the Senate Committee on Environment and Public Works' Subcommittee on Toxic Substances, environmental Oversight, Research and Development Hearing on Pesticides.

Agriculture's Contribution to Water Quality Protection: Lessons from the NRC Report Alternative Agriculture. October 3, 1989.Invited testimony before a joint hearing of the House Committee on Agriculture's Subcommittee on Department Operations, Research, and Foreign Agriculture, and the House Committee on Science and Technology's Subcommittee on Natural Resources, Agricultural Research, and the Environment.

Unraveling Delaney's Paradox: Unfinished Business. October 19, 1989. Invited testimony before the House Committee on Agriculture's Subcommittee on Department Operations, Research, and Foreign Agriculture.

Opportunities to Protect Water Quality: Lessons from the NRC Report Alternative Agriculture. October 24, 1989. Invited testimony before a hearing of the Senate Committee on Agriculture, Nutrition, and Forestry's Subcommittee on Conservation and Forestry.

Quality in the American Food Industry: Lessons from the NRC Alternative Agriculture Report. November 3, 1989. Paper presented at the Seventh International Conference on Gastronomy; "Tradition and Innovation in American Food and Wine--A View From the Midwest," Chicago, Illinois.

Beware the Future: Pesticides, Public Policy, and Pest Management. Presented before the 14th Illinois Crop Protection Workshop sponsored by the Illinois Cooperative Extension Service, March 9-11, 1988.

Pesticide Food Safety Act of 1988. September 7, 1988. Invited testimony before the Subcommittee on Department Operations, Research, and Foreign Agriculture, Committee on Agriculture, U.S. House of Representatives.

Florida's Food Safety Challenges. September 27, 1988. Speech presented at the 45th Annual Convention of the Florida Fruit and Vegetable Association in Naples, Florida.

Pesticide Regulatory Policy: Creating a Positive Climate for Innovation. Presented before the Conference on Technology and Agricultural Policy on December 12, 1986. Published in Technology and Agricultural Policy: Proceedings of a Symposium, 1990, pp. 122-140.

Federal-State Cooperation in the Regulation of Pesticides, chapter in the Primer Agricultural Chemicals and the Midwestern States. Proceedings of a conference held March 27-28, 1987.

Major Board on Agriculture NAS/NRC Reports

Soil Conservation: An Assessment of the National Resources Inventory, Volumes 1 and II (1986)

Pesticide and Groundwater Quality: Issues and Problems in Four States (1986)

Pesticide Resistance: Strategies and Tactics for Management (1986)

Agricultural Biotechnology: Strategies for National Competitiveness (1987)

Educating the Next Generation of Food and Agricultural Professionals (1987)

Regulating Pesticides in Food: The Delaney Paradox (1987)

Designing Foods: Animal Product Options in the Marketplace (1988)

Understanding Agriculture: Education in the Secondary Schools (1988)

Alternative Farming (1989)

Investing in Research: A Proposal to Strengthen the Agricultural, Food, and

Environmental System (1990)

Partial List of Hearings Conducted by the Subcommittee on Department Operations, Research, and Foreign Agriculture

Agricultural Research System

Overnight Hearings on Agricultural Research -- June 22, 23, 28, 29, 1982.

Review of the Report "Extension in the Eighties," June 30, 1983 (Ser. No. 98-28).

Extension Service Oversight, February 17 and March 9 and 10, 1982 (Ser. No. 97-EEE).

National Plant Germplasm System, June 24, 1981 (Ser. No. 97-W).

1981 Farm Bill, agricultural research and extension titles, March 19 and 20, June 6 and 28, 1981 (Ser. No. 97-G, Part 8).

H.R. 1309 on the 1890 land grant colleges, June 4, 1981. Resident instruction hearings, February, 1984.

Information Management

"Information Technology for Agricultural America." Workshop and Committee Print, December 1982.

Application of Computer Based Information Systems and Services in Agriculture, May 19 and 20, 1982.

Natural Resources Data Bases, June 2, 1981 (Ser. No. 97-K).

Substantial portions of "Sustainable Agricultural Systems," April 22 and 27, 1982 (Ser. No. 97-PPP).

Natural Resource Conservation

Sustainable Agricultural Systems, April 16, 22, and 27, 1982 (Ser. No. 97-PPP).

Groundwater Quality and Quantity Issues, July 23, 1981 (Ser. No. 97-7).

Salinity Control in the Colorado River Basin, June 10, 1981 (Ser. No. 97-L).

Effects of Air Pollution on Agricultural Productivity, July 9, 1981 (Ser. No. 97-TT).

Pesticide Regulation and Pest Control Issues

EPA Pesticide Regulatory Program Study, December 17, 1982 (Ser. No. 97-NNN).

Regulation of Pesticides, February 22 and 23, April 6, June 9, July 6 and 27, 1982 (Four volumes, Ser. No. 98-).

Federal Insecticide, Fungicide, and Rodenticide Hearings in the 97th Congress, June 16 and 18, July 16 and 22, September 4, 1981, February 4, 1982 (Ser. No. 97-R, Parts I, II, III).

APHIS Oversight, July 28, 1983 (Ser. No. 98-).

Miscellaneous APHIS programs, September 21, 1982 (Ser. No. 97-FFFF). Compensation for Quarantine Plant Pest Loss; Protection Against Plant Pests, October 1, 1981.

Nutrition Research

Federal Commitment to Human Nutrition Research. June 23, 1982 (Ser. No. 97-WWW).

Reorganization of USDA's Food and Nutrition Service, September 17, 1981. Committee on Science and Technology Implementation Plan for a National Nutrition Status Monitoring System, June 24, 1981 (Ser. No. 97-N).

Appendix B. Litigation Experience

- 1. Peterson, et al. v. BASF Corp. Plaintiff's attorney, Hugh Plunkett, Lockridge Grindal Nauen, St. Paul, Minnesota. Trial Ada, Minnesota, in the District Court for Northeastern Minnesota (Red River Valley).
- 2. James E. Fox, et al. v. Cheminova, Inc USDC, EDNY Case Number CV 00-5145, plaintiff's attorney Kevin Huddel, Jones, Verras, and Freiberg, LLC, New Orleans, Louisiana.
- 3. Ricardo Ruiz Guzman individually, Martin Martinez individually, and Miguel Farias and Ignacia Farias, husband and wife v. Amvac Chemical Corporation. Plaintiff's attorney, Richard Eymann, Eymann, Allison, Hunter, Jones, P.S., Spokane, Washington.
- 4. United Industries v. Dow AgroSciences. Plaintiff's attorney, Dudley Von Holt, Thompson Coburn LLP, St. Louis, Missouri.
- 5. Hardin, et al. v. BASF, U.S. District Court for the Eastern District of Arkansas. Plaintiff's attorney, William French, Looper Reed and McGraw, Dallas, Texas.
- 6. Timm Adams, et al. vs. U.S.A., et al., Idaho U.S.D.C. Case No. CIV 03-049-E-BLW, Plaintiff's attorneys, Holland and Hart, Boise, ID and Denver, CO.
- 7. Jim Aana, et al., vs. DuPont Pioneer and Gay Robinson, Inc. Civil No. CV12 00231 LEK-BMK, United States District Court, District of Hawaii.
- 8. Conagra Foods, Inc, Case re Wesson oils, No. 11-cv-05379-MMM, U.S. District Court Central District of California Western District.
- 9. Laura Eggnatz, Katrina Garcia, and Julie Martin v. Kashi Company. Civil Case No.: 12-21678-CIV-Lenardo/O'Sullivan, U.S. District Court, Southern District of Florida, Miami Division.
- 10. GROCERY MANUFACTURERS ASSOCIATION, SNACK FOOD ASSOCIATION, INTERNATIONAL DAIRY FOODS ASSOCIATION, and NATIONAL ASSOCIATION OF MANUFACTURERS, Plaintiffs, v. WILLIAM H. SORRELL, in his official capacity as the Attorney General of Vermont, PETER E. SHUMLIN, in his official capacity as Governor of Vermont; TRACY DOLAN, in her official capacity as Commissioner of the Vermont Department of Health;

and JAMES B. REARDON, in his official capacity as Commissioner of the Vermont Department of Finance and Management, Case No. 5:14-cv-117, United States District Court for the State of Vermont.

11. Barron v. Snyder's-Lance, Inc. No. 0:13-cv-62496-Leonard-Goodman (S.D. Fla.).

Appendix C. References Cited in Report and Additional Documents Relied On

Martin Marchman Anderson et al, *Feasibility of new breeding techniques for organic* farming, Trends in Plant Science (article in press).

Henrik Mielby et al, *Multiple aspects of unnaturalness: are cisgenic crops* perceived as being more natural and more acceptable than transgenic crops?, 30 Agric Hum Values 471 (2013).

Paul Rozin et al, *European and American perspectives on the meaning of natural*, 59 Appetite 448 (2012).

Nicole Kronberger et al, *How Natural is "More Natural"? The Role of Method, Type of Transfer, and Familiarity for Public Perceptions of Cisgenic and Transgenic Modification*, 36 Science Comm. 106 (2014).

Helena Siipi, Dimensions of Naturalness, 13 Ethics & The Env't 71 (2008).

Press Release, CellPress, Scientists see a natural place for 'rewilded' plants in organic farming (May 26, 2015).

P. F. Van Haperen et al, *Reconstruction of the Ethical Debate on Naturalness in Discussions About Plant-Biotechnology*, 25 J. Agric. Envtl. Ethics 97 (2012).

Reference Resource: Monsanto Supplemental Information for Investors, Monsanto (Jan. 5, 2012).

Monsanto Biotechnology Trait Acreage: Fiscal Years 1996-2009, Monsanto (Oct. 7, 2009).

"Genetically engineered varieties of corn, upland cotton, and soybeans, by State and for the United States, 2000-14", U.S. Dep't of Agric. (July 14, 2014) (cotton and soybean data excluded).

"Petition for Determination of Nonregulated Status for Corn Rootworm Protected and Glyphosate Tolerant MON 87411 Maize", Monsanto (Dec. 18, 2013).

Channa Jayasumana et al, *Hypothesis: Glyphosate, Hard Water and Nephrotoxic Metals: Are They the Culprits Behind the Epidemic of Chronic Kidney Disease of*

Unknown Etiology in Sri Lanka?, 11 Int. J. Env. Res. Public Health 2125 (2014).

Channa Jayasumana et al, *Drinking well water and occupational exposure to Herbicides is associated with chronic kidney disease*, Envt'l. Health 2015 (formatted version forthcoming).

Gina Kolata, *A Proposal to Modify Plants Gives G.M.O. Debate New Life*, N.Y. Times, May 28, 2015, http://www.nytimes.com/2015/05/29/health/a-proposal-to-modify-plants-gives-gmo-debate-new-life.html.

Bohn, T., Cuhra, M., Traavik, T., Sanden, M., Fagan, J., and Primicerio, R. 2014. "Compositional differences in soybeans on the market: Glyphosate accumulates in Roundup Ready GM soybeans," *Food Chemistry*, Vol. 153, pages 207-215.

Letter from Monsanto to Mr. Michael A. Lidsky, Deputy Director, BBEP, APHIS, USDA, Subject: *Petition for Determination of Non-Regulated Status: Insect Protected Corn Line MON 80100* (March 30, 1995).

Costa et al. 2010. "Detection of genetically modified soybean DNA in refined vegetable oils," *Eur Food Res Technology*, Vol. 230: pages 915-923.

"Biopesticides Registration Action Document: Cry1Ab and Cry1F *Bacillus thuringiensis* (*Bt*) Corn Plant-Incorporated Protectants", U.S. Envt'l. Prot. Agency (Sept. 2010).

Letter from Dennis M. Keefe to Neal Carter, Okanagan Specialty Fruits, *Biotechnology Consultation Agency Response Letter BNF 000132* (March 20, 2015).

Chris DiFonzo and Eileen Cullen, *Handy Bt Trait Table* (Jan. 2012).

Kathryn Guyton, et al, Int'l Agency for Research on Cancer Monograph Working Group, *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon, and Glyphosate*, 16 The Lancet Oncology 490 (2015), *available at*: http://dx.doi.org/10.1016/S1470-2045(15)70134-8.

Press Release, International Agency for Research on Cancer, *IARC Monographs Volume 112: evaluation of five organophosophate insecticides and herbicides* (March 20, 2015).

Policy Memorandum from Miles McEvoy, Deputy Director of the USDA, Subject: Cell Fusion Techniques used in Seed Production (Feb. 1, 2013).

Draft Guidance from USDA, Decision Tree for Classification of Materials as Synthetic or Nonsynthetic, NOP 5033-1.

McEvoy, Miles. May 17, 2013. USDA Blog - "Organic 101: Can GMOs Be Used in Organic Products?" Access at: http://blogs.usda.gov/2013/05/17/organic-101can-gmos-be-used-in-organic-products/

Monsanto, Product Patents, http://www.monsanto.com/products/pages/productpatents.aspx (last visited Mar. 19, 2014).

Paul Oldham & Anthony Mark Cutter, Mapping Global Status and Trends in Patent Activity for Biological and Genetic Material, 2 Genomics, Society and Policy 62 (2006).

Paul Oldham et al, Biological Diversity in the Patent System, 8 PLOS e78737 (Nov. 2013).

Memorandum from Andrew H. Hirshfeld, Deputy Commissioner for Patent Examination Policy, U.S. Patent and Trademark Office, Subject: 2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products (March 4, 2014).

Litigation Documents

GMI KIX00000150

GMI KIX00000186

GMI_KIX00000191

GMI_KIX00099183

GMI_KIX00099185

GMI_KIX00099187

GMI KIX00099188

GMI KIX00099189

GMI KIX00099190

GMI KIX00099192

GMI_KIX00099193

GMI_KIX00099194

GMI_KIX00099195

- GMI_KIX00099197
- GMI_KIX00099198
- GMI_KIX00099199
- GMI KIX00099201
- GMI_KIX00099203
- GMI KIX00099204
- GMI_KIX00099205
- GMI_KIX00099206
- GMI_KIX00099208
- GMI_KIX00099209
- GMI_KIX00099214
- GMI_KIX00099214 GMI_KIX00099215
- CMI_KMX0000021
- GMI_KIX00099216
- GMI_KIX00099217
- GMI_KIX00099219
- GMI_KIX00099221
- GMI_KIX00099222
- GMI_KIX00099223
- GMI_KIX00099226
- GMI_KIX00099228

Transcript of the Deposition of Sarah Geisert, May 21, 2013.

Additional Patents

- 723572
- 736864
- 6455469
- 7250501
- 7468476
- 7531724
- 7547820
- 7517020
- 7619151
- 7667113
- 7718869
- 7807893
- 7928299
- 8035009
- 8134055
- 8288627
- 8319068
- 8362341